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EXAMINER

LI, QIAN J

ART UNIT

PAPER NUMBER

1632

16

DATE MAILED: 09/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/511,008

Applicant(s)

HAGEMAN, GREGORY S.

Examiner

Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 38-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 12, 19 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: detailed action.

DETAILED ACTION

The amendment and response filed in May 29, 2002 have been entered as Paper # 15. Claims 1 and 36 have been amended. Claims 37 and 67 have been canceled. Claims 1-36, and 38-66 are pending, claims 1-7, 9, 10, 12, 19, and 36 are under current examination.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

The specification stand objected to because of the following informalities: pages of the specification should be numbered continuously in Arabic numbers, numbering pages as 94, 94A, 94B or 98, 98A, and 98B, for example, are not legible for publication, appropriate correction to all such practice is required.

In Paper #15, the applicant indicates a substitute specification will be provided upon a notice of allowable subject matter. It is reminded that a Notice of Allowance could not be issued without the amendment of the specification.

Claim Objections

Claim 1 is objected to because of the claim recitation, "detecting one or more genotypic or phenotypic markers for macular degeneration", which embraces multiple inventions as indicated in Paper #9, upon election of the invention to be examined in the instant application, the claim should be amended to read on the elected invention.

The specification teaches that "genotypic marker", refers to "*any polymorphism or mutation that is associated with a particular disorder or disease*", whereas "*The phenotype may include...gene product which is upregulated or downregulated in the disorder or disease*" (page 18, lines 12-17), that "*polymorphism refers to the coexistence of more than one form of a gene or portion (allelic variant) thereof*" (page 19, lines 28-29). Thus, "genotypic marker" recited in the claim clearly indicates detecting changes in the nucleic acid levels in light of the specification. Since the elected invention is drawn to detection of a protein marker for diagnosis, claim 1 should be amended to read on the elected invention

Claims 1 and 36 are objected to because the recitation "perform" should be "performing".

Applicant's amendment necessitated the new ground(s) of rejection, which appear below.

Claim Rejections - 35 USC § 112

Art Unit: 1632

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9, 10, 12, 19, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosing or determining a predisposition to developing an arterial wall disruptive disorder in a subject by performing a radiological procedure or an ophthalmological procedure on the subject, does not reasonably provide enablement for diagnosing or determining a predisposition to developing an arterial wall disruptive disorder in a subject by detecting the presence of drusen or detecting one or more phenotypic markers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In Paper #15, the applicant traverses the rejections on the ground that "the procedures recited in the newly added claim elements are all well known in the art and hence enabled, that the specification has provided ample evidence substantiating the correlation between macular degeneration and arterial wall disruptive disorders, and reiterated the list on pages 67-68.

The argument has been carefully considered but found not persuasive for reasons of record advanced on pages 4-11 of Paper #13, and the following.

It is noted that the amended claims have substantially changed from originally presented invention by adding steps using conventional diagnostic methods. However, the addition of steps known in the art for diagnosis of aneurysms have not provide

Art Unit: 1632

sufficient enablement for the claimed invention, because in case the findings from MRI or ophthalmoscope are positive, the subject could be diagnosed to have an arterial wall disruptive disorder without the detection of phenotypic markers. However, in case the findings from conventional examination are negative, meaning the subject has not yet developed an arterial wall disruptive disorder, the skilled artisan still could not determine, based solely on the findings of phenotypic markers, whether the subject have a predisposition to developing an arterial wall disruptive disorder in a subject because the specification fails to establish how the markers of macular degeneration are associated with the development of arterial wall disruptive disorder, and the response fails to address the particular questions raised in the previous Office action (Paper #13).

For example, the specification fails to provide the elastin levels of liver mRNA or protein in normal or in AMD population, thus, one would not know which result considered as an increased levels of elastin mRNA, even if the patient is willing to undergo a liver biopsy to assess the elastin levels for determining a predisposition to developing AAA. The specification further fails to teach how liver elastin mRNA is associated with elastin protein expression in the arterial wall, the elastin levels in liver and arterial wall in individuals and groups of individuals having AMD+/AAA+ and AMD-/AAA+ in order to establish a relationship between markers and diseases. Lacking the aforementioned basic information, the skilled artisan could not make a diagnosis or determination for AAA predisposition without undue experimentation.

Moreover, according to working example 1 of the specification, out of 33 AMD patients, 25 do not have AAA, thus, if applying this probability to predict AAA from AMD, 75% AMD patients would not have AAA. Thus, even if the drusen is detected in the eye, the conclusion could only be that the subject is unlikely to developing AAA, such conclusion seems contrary to the instant intention. Therefore, applying AMD markers for diagnosis of AAA is highly unpredictable.

In response to the Office action regarding the discrepancy in the art of record concerning elastin levels in AAA and AMD patients, the applicant argues that the prior art teaches the elastin degradation *in situ* in the aorta aneurysm tissue, "By no means did Satta et al indicate that elastin protein expression levels in these tissues are reduced", and "It does not follow that elastin mRNA levels in liver".

It is noted that the cited prior art taught both degradation of elastin and elastin protein content, which reflect expression levels of the elastin. The specification has not provided any new method that differs from the prior art in examining protein expression in these tissues. Moreover, the cited art teaches the difficulties in using elastin as marker for diagnostic purpose. For example, *Grange et al* teach, "THERE IS CERTAINLY NO EVIDENCE FOR THE SYNTHESIS OF NEW ELASTIN FIBERS BEYOND THE PERINATAL PERIOD", that "LOW LEVELS OF ELASTIN MRNA IN ADULT AORTA" (1st paragraph in page 259). With respect to liver mRNA levels, it is noted that both *Robert et al* and *Grange et al* do teach study AA systemically, for example, *Grange et al* list the advantage and pitfalls of studying diseased tissue vs. systemic markers (Table 1), *Robert et al* particularly teach the difficulties in analyzing and correlating the systemic data to vascular disease, "WHICH

Art Unit: 1632

BLOOD PARAMETERS MIGHT BE RELATED TO VASCULAR MATRIX MODIFICATIONS?"; "WITHOUT SUCH MODIFICATIONS, ECM PARAMETERS WOULD NOT BECOME ACCESSIBLE FOR CLINICAL EVALUATION".

Therefore, without further evidence, how to interpret and correlate "the increased elastin mRNA levels in the liver" with AAA, and whether it could be used as a diagnostic marker for AAA is in serious question. In conclusion, the specification fails to address the critical questions raised in the aforementioned references, the skilled artisan in the relevant art could not practice the invention without first carrying out extensive undue experimentation.

The applicant further argues that the legal standard for judging whether disclosed data is sufficient to satisfy the enablement requirement of 35 U.S.C., first paragraph, is whether one of skill in the art would accept the data as reasonably correlating to the asserted claims.

In response, M.P.E.P. (MPEP 2164.02, 03) teaches the legal standard for evaluating the statutory requirement for enablement disclosure,

"THE TEST OF ENABLEMENT IS WHETHER ONE REASONABLY SKILLED IN THE ART COULD MAKE OR USE THE INVENTION FROM THE DISCLOSURES IN THE PATENT COUPLED WITH INFORMATION KNOWN IN THE ART WITHOUT UNDUE EXPERIMENTATION." (UNITED STATES V. TELETRONICS, INC., 857 F.2D 778, 785, 8 USPQ2D 1217, 1223 (FED. CIR. 1988)). "DETERMINING ENABLEMENT IS A QUESTION OF LAW BASED ON UNDERLYING FACTUAL FINDINGS". IN RE VAECK, 947 F.2D 488, 495, 20 USPQ2D 1438, 1444 (FED. CIR. 1991); ATLAS POWDER CO. V. E.I. DU PONT DE NEMOURS & CO., 750 F.2D 1569, 1576, 224 USPQ 409, 413 (FED. CIR. 1984). One aspect of such factual evidence to be considered is "IF LITTLE IS KNOWN IN THE PRIOR ART ABOUT THE NATURE OF THE INVENTION AND THE ART IS UNPREDICTABLE, THE SPECIFICATION WOULD NEED MORE DETAIL AS TO HOW TO MAKE AND USE THE INVENTION IN ORDER TO BE ENABLING". "AN APPLICANT'S SPECIFICATION MUST ENABLE A PERSON SKILLED IN THE ART TO MAKE AND USE THE CLAIMED INVENTION WITHOUT UNDUE

Art Unit: 1632

EXPERIMENTATION.(...) AS SUCH, THE DISCLOSURE MUST TEACH A PERSON SKILLED IN EACH ART HOW TO MAKE AND USE THE RELEVANT ASPECT OF THE INVENTION WITHOUT *UNDUE* EXPERIMENTATION. FOR EXAMPLE, TO ENABLE A CLAIM TO A PROGRAMMED COMPUTER THAT DETERMINES AND DISPLAYS THE THREE-DIMENSIONAL STRUCTURE OF A CHEMICAL COMPOUND, THE DISCLOSURE MUST

- ENABLE A PERSON SKILLED IN THE ART OF MOLECULAR MODELING TO UNDERSTAND AND PRACTICE THE UNDERLYING MOLECULAR MODELING PROCESSES; AND
- ENABLE A PERSON SKILLED IN THE ART OF COMPUTER PROGRAMMING TO CREATE A PROGRAM THAT DIRECTS A COMPUTER TO CREATE AND DISPLAY THE IMAGE REPRESENTING THE THREE-DIMENSIONAL STRUCTURE OF THE COMPOUND.

IN OTHER WORDS, THE DISCLOSURE CORRESPONDING TO EACH ASPECT OF THE INVENTION MUST BE ENABLING TO A PERSON SKILLED IN EACH RESPECTIVE ART. (MPEP 2106.B.2)

Therefore, for reasons of record and set forth in the proceeding paragraphs, the present specification fails to meet the enablement requirement commensurate with the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9, 10, 12, 19, and 36 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite even though amended claims 1 and 36 recite positive steps, however, it is unclear the basis of the last step, i.e. how to evaluate the findings of steps 1, 2, and 3, so that one could diagnose the subject as having a macular degeneration, particularly when the results from the first two steps are negative

Art Unit: 1632

findings. Thus, the metes and bounds of the claim are unclear.

Claims 1 and 36 are vague and indefinite because of the claim recitation, "anatomically targeted procedure", the specification does not define the term, the metes and bounds of the claim is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of claims 1, 2, 4, 6, 7, 9, 10, 36, 37, and 67 under 35 U.S.C. 102(a) as being anticipated by *Satta et al* (Eur J Vasc Endovasc Surg 1998 Apr;15:313-9) is withdrawn in view of the amendment of claims.

The prior rejection of claims 1, 2, 6, 7, 9, 10, 36, 37, and 67 under 35 U.S.C. 102(b) as being anticipated by *Juvonen et al* (Eur J Vasc Surg 1994 Jan;8:70-7) is withdrawn in view of the amendment of claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1632

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The prior rejection of claims 1-7, 9, 10, 36, 37, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Satta et al* or *Juvonen et al* as applied to claims 1, 2, 4, 6, 7, 9, 10, 36, 37, and 67 above, and further in view of *ENCYCLOPAEDIA BRITANNICA*, is withdrawn in view of the amendment of claims.

Claims 1-7, 9, 10, 12, 19, and 36, are rejected under 35 U.S.C. 103(a) as being unpatentable over *Nitatori et al* (Radiation Med Jan-Feb 1999;17:9-14), in view of *Schneider et al* (Ophthalmologica 1997;211:115-8), *Cunningham et al* (IDS/AT), *Vingerling et al* (Am J Epidemiol 1995;42:404-9), and further in view of *Newsome et al* (IDS/BQ), and *Satta et al* (Eur J Vasc Endovasc Surg 1998 Apr;15:313-9).

The claims are drawn to a method for diagnosing or determining a predisposition to developing an arterial wall disruptive disorder in a subject comprising performing a radiological procedure on the subject to detect a symptom indicative of arterial wall disruptive disorder; performing an ophthalmological procedure on the subject to detect presence of drusen; and detecting phenotypic markers for macular degeneration, wherein the marker is one or more drusen associated markers, particularly elastin, wherein the detection is performed by an immunoassay, whereby the subject is diagnosed to have or a predisposition to developing an arterial wall disorder, wherein said arterial wall disorder is selected from the group consisting of an aortic (AAA or TAA), a peripheral, a visceral, and an intracranial aneurysm; wherein said macular

Art Unit: 1632

degeneration is AMD, preferably neovascular form, characterized by disciform scars and/or choroidal neovascularization.

Nitatori et al teach diagnosis of an arterial wall disruptive disorder (both thoracic and abdominal aortic dissecting aneurysm) in a subject by performing a radiological test using magnetic resonance imaging (MRI) technique. They teach, "RECENT PROGRESS IN HIGH-SPEED VISUALIZATION BY MRI HAS ENABLED THE DIAGNOSIS OF RAPIDLY MOVING ORGANS, SUCH AS THE HEART AND MAJOR BLOOD VESSELS, AND NUMEROUS REPORTS OF THE USE OF THIS TECHNIQUE IN CLINICAL CASES WITH AORTIC DISSECTION HAVE APPEARED", the teaching clearly illustrated the state of the pertinent art, and that the skilled artisan knows using radiological procedure for diagnosis of an arterial wall disruptive disorder. *Nitatori et al* do not teach macular degeneration.

Cunningham et al first reported the co-existence of ophthalmic artery aneurysm (peripheral aneurysm) and drusen of retina, and how an aneurysm of the ophthalmic artery might have been overlooked because of the presence of drusen. *Cunningham et al* teach, "PATIENTS WITH SUCH FINDINGS DESERVE CAREFUL OPHTHALMIC AND NEUROLOGICAL EVALUATION TO SCREEN OUT MORE SERIOUS UNDERLYING DEFECTS" (Summary). *Cunningham et al* do not teach using drusen as the diagnosis for vascular disease, but illustrated that ophthalmological procedure is an effective tool in diagnosis of peripheral artery aneurysm. *Schneider et al* teach the diagnosis and differential diagnosis of AMD and retinal arterial macro-aneurysms. From ophthalmoscope, they could see mild arteriosclerotic vascular changes, the presence of disciform lesion (disciform scar) of AMD, and spontaneously pulsating macroaneurysm in the first patient; and neovascular

Art Unit: 1632

AMD and a pulsatile retinal artery macroaneurysm in the video-angiographic arterial and venous return images in the second patient. *Schneider et al* go on to teach that many elderly patients have co-existing conditions of AMD, hypertension, arteriosclerosis, "CONDITIONS THAT ARE ALSO PRESENT IN THE MAJORITY OF PATIENTS WITH RETINAL MACROANEURYSMS" (Discussion). *Vingerling et al* teach that AMD is associated with atherosclerosis, an arterial wall disruptive disorder, in a population-based study. They teach that "IN SUBJECTS YOUNGER THAN AGE 85 YEARS, PLAQUES IN THE CAROTID BIFURCATION (artery plaque) WERE ASSOCIATED WITH A 4.7 TIMES INCREASED PREVALENCE ODDS OF MACULAR DEGENERATION; THOSE WITH PLAQUES IN THE COMMON CAROTID ARTERY SHOWED AN INCREASED PREVALENCE ODDS OF 2.5" (abstract). *Cunningham et al*, *Schneider et al*, and *Vingerling et al* all teach diagnosis of aneurysm using ophthalmic procedure and clearly set forth the association of AMD and vascular disruptive disorder, but do not teach detection of phenotypic markers.

Satta et al and *Newsome et al* investigate elastin and other ECM components using immunohistochemical study to explore underlying mechanisms of AAA and AMD. *Satta et al* teach a method comprising detecting elastin levels in human abdominal aortic aneurysm. *Newsome et al* teach a method comprising detecting collagens and elastin in drusen by immunoassays. The teachings of *Satta et al* and *Newsome et al* illustrated that the skilled artisans use similar markers for study AAA or AMD.

Evidently, at the time of the effective filing date of the present application, it is known in the art to use a radiological procedure, such as MRI, for diagnosis of an aortic arterial wall disruptive disorder; it is also known in the art that ophthalmic procedures,

Art Unit: 1632

such as ophthalmoscope and video-angiography, could be used for diagnosis of peripheral aneurysm; it is also known in the art that markers of extra-cellular matrix, such as elastin and collagen, could be used for study both AMD and AAA, and that AMD and AAA could co-exist and have shared risk factors as taught by *Cunningham et al*, *Schneider et al*, *Vingerling et al*, *Satta et al*, and *Newsome et al*. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method taught by *Nitatori et al* and *Schneider et al* for diagnosis of aortic and the peripheral aneurysm with a reasonable expectation of success, and further detecting ECM markers for understanding of the disease mechanisms. The skilled artisan would have been motivated to combine because two methods target different portions of the arteries of a subject, and because the ophthalmic procedure is direct, cost effective, and non-invasive. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1632

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
August 23, 2002


JAMES KETTER
PRIMARY EXAMINER